International Accreditation Forum

ISO 13485 IAF MDCAS

Medical Device Conformity Assessment System

Concerning Conformity Assessment of Quality Management Systems for Regulatory Purposes

1st Edition 2009

"To provide opportunities to develop medical device regulations while maintaining access to safe and effective healthcare technologies".

Accredited Certification and Recognition of ISO 13485 IAF MDCAS

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Date January 4, 2010

Within medical device regulations the demand to maintain a quality management system similar to ISO 13485 is increasing. The Global Harmonization Task Force (GHTF) advocates that regulators use ISO 13485 and many countries that are developing their own harmonized medical device regulations are looking to the GHTF for guidance. What they see in the real world, however is the US FDA does not recognize ISO 13485 certificates, Canada does, but only if issued under their CMCDAS program. Japan and Europe utilize ISO 13485 audit criteria, but have add-on requirements from their own regulation and require that only their auditors be used. More and more countries are following their example, which is leading to a disastrous problem for medical device trade and the healthcare systems threatened by the legal extinction of device they use to treat their patients. As industry has to pay more for each "add-on" country during their annual audit, or in some cases pay for a completely new inspection, healthcare practitioners are now caught in the middle, along with the industry that supplies them. Industry has to make tough decisions as to which markets it can afford to stay in, and which countries it will not be able to legally supply. With as many as 140 countries still without fully developed medical device regulations, and the GHTF suggesting use of ISO 13485, how many will develop their own national regulation to this international Quality Management System standard Will we have pay for separate pay for Egyptian, South African, or Thai inspections too?

Before the problem can be solved, we have to understand why regulators create their own national quality system regulations? The answer is actually quite simple. Regulators can't fully trust what they can't see. They introduce their own quality system regulations so they have access to audit information, control over the competency of the auditors, and can ensure that some additional national requirements are assessed during the audit. The solution is in creating a more credible and transparent certification process that covers what regulators need. This is where Accreditation activities come into play.

The International Accreditation Forum is an international cooperation of accreditation bodies comprised of representatives from more than 50 countries. These Accreditation Bodies cooperate to create impartial and more credible certification programs. What is accreditation? Accreditation is about building trust in conformity assessment activities. A more accurate definition is;

Accreditation *– an independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies and in turn the value and credibility of the corresponding attestations of conformity – underpins trust in the global market.*

The International Accreditation Forum vision statement of "Certified once, accepted everywhere" is based on the principle, that a credible certification is what makes mutual acceptance possible.

Right now the IAF is creating a new accredited certification program for ISO 13485, referred to as the IAF Medical Device Conformity Assessment System (MDCAS). It uses ISO 17011, ISO 17021 as harmonized standards and adds some relevant requirements from the GHTF Study Group 4 to ensure the accreditation activities are properly aligned for the medical device sector.

ISO 13485 IAF MDCAS is designed to serve medical device regulatory purposes. As there are many IAF member accreditation bodies spread throughout Europe, Asia, North America, South America, Africa and Australia, it will be the most accessible *and credible* accreditation for medical

device QMS that has ever been created. But, why would regulators choose to use this? What does IAF MDCAS offer them?

For countries that formally recognize ***"ISO 13485 IAF MDCAS"*** certificates in their regulations, they alone are permitted access to assessment and audit reports created by the Accreditation Bodies. (AB) and Conformity Assessment Bodies (CAB). IAF MDCAS introduces enforceable contractual arrangements between the AB and CAB, to provide regulators with information upon request. CABs of course would simply model their existing contractual arrangements with medical device manufacturer to ensure their existing agreements for transparency includes regulators that formally recognized ISO 13485 IAF MDCAS certificates in their regulations.

IAF MDCAS is the first ISO 13485 certification that guarantees transparency to regulators that formally recognize this unique certificate. If a regulation does not identify "ISO 13485 IAF MDCAS" certificates in their regulation, they are not entitled to anything. This system gives regulators a necessary incentive to avoid creating their own inspection program in order to get the same level of transparency that they would have under a national QMS regulation.

Industry benefits, because the audit for ISO 13485 does not change. There are no add-on audit requirements for medical device industry under the IAF MDCAS accredited certification system. ISO 13485 IAF MDCAS certification audits only changes when the ISO 13485 standard changes. The IAF MDCAS criteria for Accreditation Bodies, Conformity Assessment Bodies and Industry can change independently from each other. Medical Device industry only has to focus on ISO 13485. Keep in mind that ISO 13485 always requires manufactures to consider the regulations of the markets they are selling their products to. It is truly the most credible, harmonized and transparent certification system ever made available to regulators and industry.

The Global Harmonization Task Force has been at work since 1992 to create guidance on how to regulate medical devices. The International Accreditation Forum is using this guidance as the foundation for its IAF MDCAS program. The IAF has sometimes been referred to as "The Global *Recognition* Task Force", since accreditation creates the necessary credibility that contributes to global recognition. Certified once, accepted everywhere cannot succeed without using accreditation standards and the accreditation bodies that enforce more credible certification.

ISO 13485 IAF MDCAS was created as a "Field of dreams - *Build it and they will come.* Regulators and industry both need a common program for certification that is worthy of global [Multilateral] recognition. The IAF also has a highly structured Multilateral Recognition Agreement system that will serve the needs of public health worldwide as well as international trade. Mutual acceptance also removes a barrier to healthcare as well, since many medical device manufacturers simply would not be able to afford to pay for an inspection for each and every country that demands one. The continued development of national barriers to trade cannot continue without putting at risk, the very same people these regulations were meant to help. Accredited certification gives regulators a valuable tool – credible, transparent certification that is worthy of global recognition.

As of October 18th 2009, the first drafts of the ISO 13485 IAF MDCAS were completed. Over the course of the next 12 months, these drafts will be reviewed and modified until they are ready for vote and acceptance by the 50 to 60 participating member countries of the IAF. The GHTF is also involved in the comment period. During this final stage, regulators from around the world will be introduced to the benefits of ISO 13485 IAF MDCAS program. The IAF has even created an ISO 13485 IAF MDCAS handbook, which explains how the program works, and should be introduced into national medical device regulations.

ISO 13485 MDCAS Certification

Benefitting healthcare systems worldwide under the surveillance of participating regulatory authorities